

### **REMARKS**

We note that the Examiner concedes that the subject matter of claims 38 and 39 would be allowable if claim 38 were rewritten in independent form.

Claim 21 has been amended to replace "the memory" with "a memory." Support for this amendment is found in the specification at, for example, page 9, line 29 – page 10, line 17; page 14, lines 16-19; page 22, lines 16-30; page 31, line 28 – page 32, line 14; page 34, lines 24-33; and page 40, line 1 - page 41, line 2; Figure 1; and in original claim 21. *See, In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claims 15 and 35 have been amended to remove optional language to better conform to U.S. practice. These amendments do not in any way change the scope of claims 15 and 35.

Claim 42 has been amended to delete the phrase beginning with "such as...." This amendment does not in any way change to scope of claim 42.

Claim 43 has been added and recites the language deleted from claim 42. Support for this claim is found in the specification at, for example, page 40, line 25 – page 41, line 2 and claim 42. *Id.*

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

### **Objection**

The Examiner objected to Claim 21, and asserted that “the phrase ‘the memory,’ lacks antecedent basis.” (Paper No. 10 at 2.) Claim 21 has been amended to replace the phrase “the memory” with “a memory.” Accordingly, the objection has been rendered moot and should be withdrawn.

### **Indefiniteness Rejections**

Claims 15 and 35 were rejected under 35 USC § 112, second paragraph. (Paper No. 10 at 2.) In making the rejection, the Examiner asserted that “the phrase ‘optionally’ renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.” (*Id.*) Claims 15 and 35 have been amended to delete the phrase to which the Examiner objects. Accordingly, the rejection has been rendered moot and should be withdrawn.

Claim 42 was rejected under 35 USC § 112, second paragraph. (*Id.*) In making the rejection, the Examiner asserted that “the phrase ‘such as’ renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.” (*Id.*) Claim 42 has been amended to delete the phrase to which the Examiner objects. Accordingly, the rejection has been rendered moot and should be withdrawn.

**Rejections under 35 USC § 103**

Claims 1-4, 7, 13-17, 21-24, 27, and 33-37 were rejected under 35 USC § 103(a) as being unpatentable over Scharlack, U.S. Patent No. 5,828,445 ("Scharlack"). (Paper No. 10 at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Scharlack discloses "methods of determining and reporting the performance of VIS-IR spectrophotometers used to measure the concentration of hemoglobin components or fractions in blood samples. In particular, the method is used to determine the performance of CO-oximeters." Col. 1, lines 51-56. Scharlack discloses that "[e]rrors due to instrument inaccuracies, such as spectral or wavelength shift, result in characteristic errors for each hemoglobin fraction as well as each quality control. The characteristic response of the instrument to such inaccuracies can be predetermined for any specific sample." Col. 6, lines 6-10.

In making the rejection as to claims 1 and 21, the Examiner asserted that "Scharlack discloses a method for measuring and reporting co-oximeter quality control results of a spectrophotometer, particularly co-oximeter, comprising determining an absorption spectrum of a fluid quality control sample with a significant absorbance peak with a steep flank and a reference absorption spectrum of a reference quality control sample stored (col. 2, lines 5-20; col. 3, lines 45-67; col. 4, lines 34-55; col. 5, lines 1-25; Figs. 1 and 4)." (Paper No. 10 at 3.) The Examiner further asserted that Scharlack discloses that "the wavelength shift [] may be predetermined (col. 6, lines 1-15). And the error spectrum is derived from a reference and measured absorbance at each wavelength (col. 5, lines 15-25)." (*Id.*)

The Examiner then concluded that "it would be obvious that the wavelength shift is determined for the error spectrum comprises the difference between the measured and estimated spectra at each wavelength." (*Id.*)

Initially, we note that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (MPEP § 2143, 8<sup>th</sup> ed., Rev. 1, February 2003, pp. 2100-124 to 2100-125; see also MPEP § 2142.)

As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would *impel* one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). The rejection, however, fails to provide any reason why one would be motivated, let alone impelled, to modify the disclosure of Scharlack in the manner suggested by the Examiner. Thus, the rejection fails to set forth the facts and

reasoning required to support a *prima facie* case of obviousness. For this reason alone the rejection should be withdrawn.

In attempting to set forth a *prima facie* case for obviousness the Examiner is required to consider the claimed invention as a whole. "In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983)." (MPEP § 2141.02, 8<sup>th</sup> ed., Rev. 1, February 2003, p. 2100-120.) (Emphasis original.)

The Examiner concluded that "it would be obvious that the wavelength shift is determined for the error spectrum comprises the difference between the measured and estimated spectra at each wavelength." (*Id.*) The determination of the wavelength shift is not what is claimed. What is claimed is a "quality control method for a spectrophotometer" (claim 1) or a "spectrophotometer" (claim 21). The Examiner apparently asserted only that the difference between the claimed invention and Scharlack is obvious.

Determining that a part of the claimed invention is obvious, however, does absolutely nothing to support a conclusion that the claimed invention as a whole is obvious. Having failed to consider the claimed invention as a whole, the rejection failed to even assert that the claimed invention is obvious. For this additional reason the rejection is deficient and should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness **must** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993).

Scharlack discloses that an error spectrum may be determined from the "difference between the measured and estimated absorbance spectrum at each wavelength." Col. 5, lines 21-23. The estimated absorbance spectrum is determined from the apparent concentration, which is determined from the best fit of the measured and standard spectrum. Col. 5, lines 5-20. Scharlack discloses that this error spectrum, however, is for a blood sample made up of various components and the spectrum is therefore made up of the "relative contributions of each blood component spectrum." Accordingly, an error matrix is required to account for the errors attributed to the various components found in blood. Col. 5, lines 28-67.

Contrary to the Examiner's assertion, there is nothing in Scharlack which discloses or suggests "that the wavelength shift is determined for the error spectrum comprises the difference between the measured and estimated spectra at each wavelength." Scharlack discloses that a measured spectrum may be used to determine an estimated spectrum from a standard spectrum and that the difference between the estimated spectrum and the measured spectrum may be used to determine an error spectrum. Scharlack also notes that "[e]rrors due to instrument

inaccuracies, such as spectral or wavelength shift, result in characteristic errors ... characteristic response of the instrument to such inaccuracies can be predetermined for any specific sample." Col. 6, lines 4-15. Scharlack does not disclose or suggest that these inaccuracies may be determined from the error spectrum, much less that they may be determined from the measured spectrum and the standard spectrum alone. In fact Scharlack does not disclose any method at all for determining the inaccuracies, including wavelength shift. For this additional reason, the rejection should be withdrawn.

In making the rejection as to claims 2 and 22, the Examiner asserted only that "Scharlack discloses everything as above (see claims 1 and 21). In addition, Scharlack discloses the error spectrum is determined from an absorption spectrum and a predetermined mathematical parameter (col. 4, lines 35-65; col. 5, lines 1-25)." (*Id.*)

As is well settled, "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." (MPEP § 2143.03, 8<sup>th</sup> ed., Rev. 1, February 2003, p. 2100-128.) Accordingly, for the reasons set forth above in relation to the rejection of claims 1 and 21, from which claims 2 and 22 depend, respectively, the rejection must be withdrawn.

As noted above, the claimed invention as a whole must be considered to make out a *prima facie* case for obviousness. The Examiner, however, has not considered claims 2 and 22 as a whole. Instead the Examiner has asserted that a limitation of claims 2 and 22 is found in Scharlack, and merely combined that assertion with his earlier argument as to claims 1 and 21. Accordingly, claims 2 and 22 have

been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claims 2 and 22 in parts, he failed to even assert that the claims as a whole are obvious. At best, the rejection asserts that claims 1 and 21 are obvious and that the limitation of dependent claims 2 and 22 are disclosed in Scharlack. Even if the Examiner's position is accepted as true, which it is not, the rejection failed to even assert that these claims as a whole are obvious. For this reason also, the rejection should be withdrawn.

In making the rejection as to claims 3-4 and 23-24, the Examiner asserted that "Scharlack discloses everything as above (see claims 2 and 22)." (*Id.*) The Examiner then asserted that "Scharlack discloses the mathematical parameter is a coefficient vector (col. 5, lines 25-60)" and as to "the vector fulfilling the equation whereas the wavelength shift equals the vector times the absorbance spectrum, Scharlack discloses the equations 6a and 6b and 3 (col. 5, lines 11, 47, and 52)." (*Id.*) The Examiner then concluded that "[i]t would be obvious to one skilled in the art at the time the invention was made that wavelength shift equals the vector times the absorbance spectrum for the substitution of equation 3 into equation 6a gives the error spectrum equaling a coefficient vector times the absorbance spectrum." (*Id.* at 3-4.)

As noted above, if an independent claim is nonobvious, then any claim depending from it is also nonobvious. Accordingly, for the reasons set forth above in relation to the rejection of claims 1-2 and 21-22, from which claims 3-4 and 23-24 depend, respectively, the rejection must be withdrawn.



As previously noted, the claimed invention as a whole must be considered in making a *prima facie* case for obviousness. However, the Examiner has merely reasserted his previous rejection of claims 2 and 22 and asserted, separately, that the limitations of dependent claims 3-4 and 23-24 are obvious. Accordingly, claims 3-4 and 23-24 have been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claims 3-4 and 23-24 in parts, he failed to even assert that the claims as a whole were obvious. For this reason also, the rejection should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a).

Scharlack discloses that a measured spectrum may be used to determine an estimated spectrum from a standard spectrum and that the difference between the estimated spectrum and the measured spectrum may be used to determine an error spectrum. Scharlack also notes that "[e]rrors due to instrument inaccuracies, such as spectral or wavelength shift, result in characteristic errors ... characteristic response of the instrument to such inaccuracies can be predetermined for any specific sample." Col. 6, lines 4-15. Scharlack does not disclose or suggest that these inaccuracies may be determined from the error spectrum, much less that they may be determined from the measured spectrum and the standard spectrum alone.

In fact, Scharlack does not disclose any method at all for determining the inaccuracies, including wavelength shift. Contrary to the Examiner's assertion, there is

nothing Scharlack which discloses or suggests the "substitution of equation 3 into equation 6a." Therefore, the Examiner has not offered the requisite facts or reasoning to support his conclusion that it is obvious that "wavelength shift equals the vector times the absorbance spectrum." For this additional reason, the rejection should be withdrawn.

In making the rejection as to claims 7 and 27, the Examiner asserted that "Scharlack discloses everything as above (see claims 1 and 21)." (*Id.* at 4.) The Examiner acknowledged, however, that Scharlack "is silent concerning normalization, but discloses that values are made nominal are set to those values observed in normal human blood (col. 3, lines 1-5) and well-known mathematical techniques of fitting spectra can be used (col. 5, lines 1-10)." (*Id.*) The Examiner then concluded that "it will be obvious to one skilled in the art that the wavelength shifts is determined after normalization of the determined spectrum with an estimate of the dye, for values are set to those values in normal human blood, and normalization is a well-known mathematical technique." (*Id.*)

As noted above, if an independent claim is nonobvious, then any claim depending from it is also nonobvious. Accordingly, for the reasons set forth above in relation to the rejection of claims 1 and 21, from which claims 7 and 27 depend, respectively, the rejection must be withdrawn.

As previously noted, the claimed invention as a whole must be considered in making a *prima facie* case for obviousness. However, the Examiner has merely reasserted his previous rejection of claims 1 and 21 and asserted, separately, that the limitations of dependent claims 7 and 27 are obvious. Accordingly, claims 7

and 27 have been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claims 7 and 27 in parts, he failed to even assert that the claims as a whole were obvious. For this reason also, the rejection should be withdrawn.

In making the rejection as to claims 13 and 33, the Examiner asserted only that "Scharlack discloses a co-oximeter (col. 3, lines 45-55)." (*Id.*)

For the reasons set forth above in relation to the rejection of claims 1 and 21, from which claims 13 and 23 depend, respectively, the rejection must be withdrawn.

In making the rejection, the Examiner made no reference to his earlier argument as to claims 1 and 21. Accordingly, the rejection asserted only that "Scharlack discloses a co-oximeter." As such the rejection failed to account for any of the limitations of claims 1 or 21, from which claims 13 and 33 depend, respectively. However, by statute "a dependent claim is construed to incorporate by reference all the limitations of the claim to which it refers." 35 USC § 112.

Because the rejection failed to account for any of the limitations of claims 1 and 21, it failed to account for each and every limitation of claims 13 and 33. That, however, was the Examiner's burden. For this additional reason the rejection should be withdrawn.

In making the rejection as to claims 14 and 34, the Examiner asserted only that "Scharlack discloses the wavelength ranges at least 500 to 640 nm (see Figs. 1-4)." (*Id.*)

For the reasons set forth above in relation to the rejection of claims 1/13 and 21/33, from which claims 14 and 34 depend, respectively, the rejection must be withdrawn.

In making the rejection, the Examiner made no reference to his earlier argument as to claims 1 and 21 or claims 13 and 33. Accordingly, the rejection asserted only that "Scharlack discloses the wavelength ranges at least 500 to 640 nm." As such the rejection failed to account for any of the limitations of claims 1/13 or 21/33, from which claims 14 and 34 depend, respectively. However, by statute "a dependent claim is construed to incorporate by reference all the limitations of the claim to which it refers." 35 USC § 112.

Because the rejection failed to account for any of the limitations of claims 1/13 and 21/33, it failed to account for each and every limitation of claims 14 and 34. That, however, was the Examiner's burden. For this additional reason the rejection should be withdrawn.

In making the rejection as to claims 15 and 35, the Examiner asserted only that "Scharlack discloses determining estimated errors in blood parameters (col. 6, lines 1-65)." (*Id.*)

For the reasons set forth above in relation the rejection of claims 1/13 and 21/33, from which claims 15 and 35 depend, respectively, the rejection must be withdrawn.

In making the rejection, the Examiner made no reference to his earlier argument as to claims 1 and 21 or claims 13 and 33. Accordingly, the rejection asserted only that Scharlack discloses "determining estimated errors in blood parameters." As such the rejection failed to account for the limitations of claims 1/13 and 21/33, from which claims 15 and 35 depend, respectively. However, by statute "a dependent claims is construed to incorporate by reference all the limitations of the claim to which it refers." 35 USC § 112.

Because the rejection failed to account for any of the limitations of claims 1/13 and 21/33, it failed to account for each and every limitation of claims 15 and 35. That, however, was the Examiner's burden. For this additional reason the rejection should be withdrawn.

In making the rejection as to claims 16-17 and 36-37, the Examiner asserted only that "Scharlack discloses determining estimated errors in blood parameter values reported by the spectrophotometer caused by a difference between  $c_{est}$  and  $c_{qc}$ , and between  $q_{est}$  and  $q_{qc}$  (col. 4, lines 35-65; col. 5, 1-25; col. 6, lines 1-15)." (*Id.*)

For the reasons set forth above in relation to the rejection of claims 1/13 and 21/33, from which claims 16-17 and 36-37 depend, respectively, the rejection must be withdrawn.

In making the rejection, the Examiner made no reference to his earlier argument as to claims 1 and 21 or claims 13 and 33. Accordingly, the rejection asserted only that Scharlack discloses "determining estimated errors in blood parameter values reported by the spectrophotometer caused by a difference between

$C_{est}$  and  $C_{qc}$ , and between  $q_{est}$  and  $q_{qc}$ .” As such the rejection failed to account for the limitations of claims 1/13 and 21/33, from which claims 16-17 and 36-37 depend, respectively.

Because the rejection failed to account for any of the limitations of claims 1/13 and 21/33, it failed to account for each and every limitation of claims 16-17 and 36-37. That, however, was the Examiner’s burden. For this additional reason the rejection should be withdrawn.

Claims 5-6, 8, 18-20, 25, 26, and 28 were rejected under 35 USC § 103(a) as being unpatentable over Scharlack in view of Maggard, WO 94/08225 (“Maggard”). (Paper No. 10 at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Scharlack is summarized above.

Maggard discloses “a method for calibrating or recalibrating a first spectrometer in light of a second spectrometer, or itself, respectively.” Page 6, lines 24-26.

In making the rejection as to claims 5-6 and 25-26, the Examiner asserted that “Scharlack discloses everything as above (see claims 4 and 24).” (Paper No. 10 at 4.) The Examiner further asserted that “Scharlack discloses the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are used (col. 5, lines 1-10).” (*Id.* at 4-5.)

The Examiner then asserted that “Maggard in a spectroscopic instrument calibration discloses that Taylor series and linear combinations of derivatives are used

in the calibration of spectra (pages 14-17)." (*Id.* at 5.) The Examiner concluded that "[i]t would be obvious to one skilled in the art that Taylor series and first derivatives are used to determine reference and therefore to determine the vectors, for Taylor series and linear combinations of derivatives of spectra are used in the calibration and fitting of spectra." (*Id.*)

Initially we note that our previous arguments as to claims 1/4 and 21/24 apply with equal force to the rejection of claims 5-6 and 25-26. As previously noted, the rejection of claims 1/4 and 21/24 is deficient for numerous reasons. The rejection of claims 5-6 and 25-26 is, itself, deficient because it expressly relies on the rejection of claims 1/4 and 21/24 and provides nothing to remedy these deficiencies. For this reason alone the rejection is deficient and must be withdrawn.

As noted above, the claimed invention as a whole must be considered to make out a *prima facie* case for obviousness. The Examiner, however, has not considered claims 5-6 and 25-26 as a whole. Instead the Examiner merely referenced his earlier rejection of claim 4 and 24 and asserted that limitations of claims 5-6 and 25-26 are found in Scharlack and Maggard. Accordingly, claims 5-6 and 25-26 have been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

As noted above, the Examiner is commanded to consider the claimed invention as a whole in making a rejection under 35 USC § 103. "The question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." (MPEP §2141.02.) The Examiner, however, merely asserted that the alleged difference

between the claimed invention and the cited document was obvious. Having failed to consider the claimed invention as a whole, the rejection failed to even assert that the claimed invention is obvious. For this additional reason the rejection is deficient and should be withdrawn.

As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would *impel* one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). The rejection fails to provide any reason why one would be motivated, let alone impelled, to combine the cited documents in the manner suggested by the Examiner. Thus, the rejection fails to set forth the required facts and reasoning required to support a *prima facie* case of obviousness. For this additional reason the rejection should be withdrawn.

In making the rejection as to claims 8 and 28, the Examiner asserted that "Scharlack discloses everything as above (see claims 1 and 21)." (*Id.*) In addition, the Examiner asserted that "Scharlack discloses errors are adjusted to new values (col. 6, lines 1-15); and the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are used (col. 5, lines 1-10)." (*Id.*)

The Examiner then asserted that "Maggard discloses that in calibrating spectra a wavelength shift, absorbance shift, is derived (pages 14-17)." (*Id.*) The Examiner concluded "[i]t would be obvious to one skilled in the art that an assigned wavelength shift for the quality control sample is compared to the wavelength shift, for



a wavelength shift of the reference spectra is derived in fitting and calibrating the reference spectrum.” (*Id.*)

Initially we note that our previous argument as to claims 1 and 21 apply with equal force to the rejection of claims 8 and 28. As previously noted, the rejection of claims 1 and 21 is deficient for numerous reasons. The rejection of claims 8 and 28 is, itself, deficient because it expressly relies on the rejection of claims 1 and 21 and provides nothing to remedy these deficiencies. For this reason alone the rejection is deficient and must be withdrawn.

As noted above, the claimed invention as a whole must be considered to make out a *prima facie* case for obviousness. The Examiner, however, has not considered claims 8 and 28 as a whole. Instead the Examiner merely referenced his earlier rejection of claim 1 and 21 and asserted that a limitation of claims 8 and 28 is found in Scharlack and Maggard. Accordingly, claims 8 and 28 have been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claims 8 and 28 in parts, he failed to even assert that the claims as a whole were obvious. The Examiner concluded that “[i]t would be obvious to one skilled in the art that an assigned wavelength shift for the quality control sample is compared to the wavelength shift, for a wavelength shift of the reference spectra is derived in fitting and calibrating the reference spectrum.” That is not what is claimed. What is claimed is a “quality control method” or a “spectrophotometer” with various recited characteristics.

As noted above, the Examiner is commanded to consider the claimed invention as a whole in making a rejection under 35 USC § 103. "The question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." (MPEP §2141.02.) The Examiner, however, merely asserted that the alleged difference between the claimed invention and the cited document was obvious. Having failed to consider the claimed invention as a whole, the rejection failed to even assert that the claimed invention was obvious. For this additional reason the rejection is deficient and should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a).

The Examiner asserted that "Maggard discloses that in calibrating spectra a wavelength shift, absorbance shift, is derived." The Examiner references pages 14 -17 of the Maggard. However, the rejection pointed to nothing on those pages which discloses a derivation of a wavelength shift or absorbance shift. In fact, Maggard discloses that these pages are devoted to showing "[t]he logic used to take a derivative of spectral absorbance data ... based on the calculus of finite differences since the data is expressed at regularly spaced intervals and is discontinuous in between the spaced intervals." Page 14, lines 10-13. Simply put, these pages are devoted to showing how discrete data points are converted into a continuous curve using derivative formulas.

The Examiner further asserted that "[i]t would be obvious to one skilled in the art that an assigned wavelength shift for the quality control sample is compared to

the wavelength shift, for a wavelength shift of the reference spectra is derived in fitting and calibrating the reference spectrum.” However, the rejection points to nothing in either Scharlack or Maggard that discloses or suggests an assigned wavelength shift.

Accordingly, the rejection failed to point out where in Scharlack and Maggard each and every element of the claimed invention is disclosed or suggested. For this reason also, the rejection should be withdrawn.

In making the rejection as to claims 18-20, the Examiner asserted that “Scharlack discloses that a first concentration and second concentration levels are used in deriving parameters (Figs. 2 and 4) ... that vectors and matrices, linear combinations of vectors, are derived (col. 5, lines 5-65) ... the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are used (col. 5, lines 1-10).” (Paper No. 10 at 5.)

“As for the calibrated vectors being linear combinations of spectra and derivative of spectra, Maggard [discloses] that in a calibrating of spectra, linear combinations of derivatives are used (pages 14-17).” (*Id.*) The Examiner then concluded that “[i]t would be obvious to one skilled in the art that calibrated vectors are determined for the reference spectrum is taken on a calibrated spectrophotometer and fit to a spectrum using known mathematical techniques.” (*Id.* at 6.)

Initially, we note that our previous argument as to the rejection of claim 1 applies with equal force to the rejection of claims 18-20, which depend from claim 1. As previously noted, the rejection of claim 1 over Scharlack is deficient for numerous reasons. The rejection of claims 18-20 is, itself, deficient because it also relies on

Scharlack and provides nothing to remedy these deficiencies. For this reason alone the rejection is deficient and must be withdrawn.

In making the rejection, the Examiner made no reference to his earlier argument as to claim 1. Moreover, the rejection is completely silent as to the limitations of claim 1, from which claims 18-20 depend. However, by statute "a dependent claim is construed to incorporate by reference all the limitations of the claim to which it refers." 35 USC § 112.

Because the rejection failed to account for any of the limitations of claim 1, it failed to account for each and every limitation of claims 18-20. That, however, was the Examiner's burden. For this additional reason the rejection should be withdrawn.

Claims 9-12 and 29-32 were rejected under 35 USC § 103(a) as being unpatentable over Scharlack in view of Campbell et al., EPO 0 132 399 ("Campbell"). (Paper No. 10 at 6.)

For the reasons set forth below the rejection, respectfully is traversed.

Scharlack is summarized above.

Campbell discloses "cooximetry quality control reagents; more particularly ... cooximetry quality control reagents which are free from blood-derived components." Page 1, lines 3-6. Campbell discloses a "cooximetry quality control composition which is free from blood-derived components and which comprises a solution of one or more dyes, which solution mimics the spectral response of whole blood at a plurality of wavelengths in the visible region." Page 6, lines 6-11.

In making the rejection, the Examiner asserted that "Scharlack discloses everything as above (see claims 1 and 21). And discloses 'n' components (col. 4, lines 25-30)." (Paper No. 10 at 6.) The Examiner then asserted that "Campbell in co-oximetry quality control reagents teaches that the quality control may contain more than one dye that mimics the spectral response of blood at a plurality of wavelengths (page 6, lines 5-10)." (*Id.*) The Examiner then concluded that "[i]t would be obvious to have a quality control sample comprise more than one dye component in order to mimic blood over a plurality of wavelengths." (*Id.*)

The Examiner then asserted "[a]s for the particular parameters, Scharlack discloses similar parameters using different variables (col. 4; equations 1 and 2; col. 5; equations 3, 4, and 5). And the estimated concentration of the dye as a linear combination may be seen in the use of vectors and matrices in the estimation of absorbance spectrum and the errors in the measured concentration of blood components (col. 5, lines 5-55) and the apparent concentrations are derived (col. 6, lines 1-55)." (*Id.*) "As for  $c_{est}$  and  $c_{qc}$ , they will be compared by the error spectrum and the relation of concentration to the absorbance spectrum (equations 4 and 5)." (*Id.*) "As for  $Q_{qc}$  and  $Q_{est}$  equaling  $s_2$  divided by  $s_1$ , fractional component concentrations are determined (equations 7-10) and as for comparing them, they will be compared by the error spectrum and the relation of concentrations to the absorbance spectrum (equations 4, 5, 7-10)." (*Id.*)

Initially we note that our previous argument as to the rejection of claims 1 and 21 apply with equal force to the rejection of claims 9-12 and 29-32. As previously noted, the rejection of claims 1 and 21 is deficient for numerous reasons. The

rejection of claims 9-12 and 29-32 is, itself, deficient because it expressly relies on the rejection of claims 1 and 21 and provides nothing to remedy these deficiencies. For this reason alone the rejection is deficient and must be withdrawn.

As noted above, the claimed invention as a whole must be considered to make out a *prima facie* case for obviousness. The Examiner, however, has not considered claims 9-12 and 29-32 as a whole. Instead the Examiner merely referenced his earlier rejection of claim 1 and 21 and asserted that limitations of claims 9-12 and 29-32 were found in Scharlack and Campbell. Accordingly, claims 9-12 and 29-32 have been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claims 9-12 and 29-32 in parts, he failed to even assert that the claims as a whole were obvious. The Examiner concluded that “[i]t would be obvious to have a quality control sample comprise more than one dye component in order to mimic blood over a plurality of wavelengths.” That is not what is claimed. What is claimed is a “quality control method” or a “spectrophotometer” with various recited characteristics.

As noted above, the Examiner is commanded to consider the claimed invention as a whole in making a rejection under 35 USC § 103. The Examiner, however, merely asserted that the alleged difference between the claimed invention and the cited document was obvious. Having failed to consider the claimed invention as a whole, the rejection failed to even assert that the claimed invention is obvious. For this additional reason the rejection is deficient and should be withdrawn.

As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would *impel* one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). The rejection fails to provide any reason why one would be motivated, let alone impelled, to combine the cited documents in the manner suggested by the Examiner. Thus, the rejection fails to set forth the facts and reasoning required to support a *prima facie* case of obviousness. For this additional reason the rejection should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In making the rejection, the Examiner asserted that "the estimated concentration of the dye as a linear combination may be seen in the use of vectors and matrices in the estimation of absorbance spectrum and the errors in the measured concentration of blood components" is disclosed at column 5, lines 5-55 of Scharlack. However, nowhere in Scharlack is an estimated concentration of the dye calculated from a linear combination of the separate dye components.

Scharlack discloses using fitting techniques to determine the best fit of the measured spectra to the standard spectra, and from this best fit, the apparent concentration of dye. Scharlack discloses "[i]n a preferred embodiment, [the apparent concentration] is obtained by a least squares analysis...." Col. 5, lines 5-10. Moreover, Scharlack discloses that the "relative contributions of each of the blood

component spectrum are the relative concentrations of each of the components. Preferably the least squares method is used.” Col. 5, lines 41-44.

The disclosure cited by the Examiner shows the calculation of an apparent dye concentration using the least squares method. There is nothing in Scharlack which discloses or suggests the calculation of the concentration of dye from the linear combination of the separate dye components. The Examiner has offered no disclosure or technical reasoning why one would be motivated to ignore the express disclosure of Scharlack to arrive at the claimed invention.

Accordingly, the rejection fails to provide the requisite evidence or reasoning to support the modification of the cited documents. For this reason also the rejection should be withdrawn.

Claims 40-41 were rejected under 35 USC § 103(a) as being unpatentable over Scharlack in view of Shaw, U.S. Patent No. 3,638,640 (“Shaw”) and in view of Shepherd et al., U.S. Patent No. 6,262,798 (“Shepherd”). (Paper No. 10 at 7.)

For the reasons set forth below the rejection, respectfully is traversed.

Scharlack is summarized above.

Shaw discloses a “spectrophotometer apparatus which measures oxygen saturation of blood in vivo and which obviates the need for making [] reference measurements.” Col. 1, lines 63-66. Shaw discloses an “oximeter apparatus which includes three semiconductor electroluminescent diodes arranged to irradiate



substantially the same area of the ear of a patient at at least three different narrow-band portions of the electromagnetic radiation spectrum.... " Col. 2, lines 31-36.

Shepherd discloses "a method and apparatus to assess the optical transmittance of a sample of unaltered whole blood at multiple wavelengths to attain an accurate measurement of its total hemoglobin concentration...." Col. 1, lines 17-20.

In making the rejection the Examiner asserted that "Scharlack discloses everything as above." (Paper No. 10 at 7.) The Examiner further asserted that Scharlack discloses that the "spectrometer detects wavelengths at least in the range 500-640 (Figs. 1-4).

And discloses compensating for errors derived (col. 6, lines 1-15). The derived spectrum in memory was taken from a calibrated spectrophotometer (col. 4, lines 35-65)." (*Id.*)

The Examiner acknowledged, however, that Scharlack "is silent concerning a spectral lamp and photodiodes that have their current ratioed." (*Id.*)

To fill the acknowledged gap, the Examiner asserted that "Shaw in an oximeter discloses that at least photodiodes are used to detect a specific wavelength and the currents ratioed to determine concentrations (col. 2, lines 35-50; col. 3, lines 15-45)." (*Id.*) The Examiner concluded that "it would be obvious to have at least photodiodes in order to ratio the currents from the specific wavelengths detected to determine a component concentration." (*Id.*)

Also to fill the acknowledged gap, the Examiner asserted that "Shepherd in a method of a spectrophotometric method for unaltered blood [discloses] using a neon lamp as light source (col. 8, lines 55-67)." (*Id.*) And concludes that "it would be

obvious to one skilled in the art at the time to have the light source for the spectrophotometric analysis comprise a neon lamp, for neon lamps are utilized as light sources in the spectral analysis of blood.” (*Id.*)

Initially we note that our previous argument as to claim 21 applies with equal force to the rejection of claims 40-41. As previously noted, the rejection of claim 21 over Scharlack is deficient for numerous reasons. The rejection of claims 40-41 is, itself, deficient because it too relies on the disclosure of Scharlack and provides nothing to remedy these deficiencies. For this reason alone the rejection is deficient and must be withdrawn.

As noted above, the claimed invention as a whole must be considered to make out a *prima facie* case for obviousness. The Examiner, however, has not considered claims 40-41 as a whole. Instead the Examiner merely referenced his earlier discussion and asserted that limitations of claims 40-41 are found in Scharlack, Shaw, and Shepard. Accordingly, claims 40-41 have been considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claims 40-41 in parts, he failed to even assert that the claims as a whole were obvious. The Examiner concluded that “it would be obvious to have at least photodiodes in order to ratio the currents from the specific wavelengths detected to determine a component concentration” and “it would be obvious to one skilled in the art at the time to have the light source for the spectrophotometric analysis comprise a neon lamp, for neon lamps are utilized as light sources in the spectral analysis of blood.” That is not what is

claimed. What is claimed is a "quality control method" or a "spectrophotometer" with various recited characteristics.

As noted above, the Examiner is commanded to consider the claimed invention as a whole in making a rejection under 35 USC § 103. The Examiner, however, merely asserted that the alleged differences between the claimed invention and the cited document were obvious. Having failed to consider the claimed invention as a whole, the rejection failed to even assert that the claimed invention was obvious. For this additional reason the rejection is deficient and should be withdrawn.

As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would *impel* one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). The rejection failed to provide any reason why one would be motivated, let alone impelled, to combine the cited documents in the manner suggested by the Examiner.

Scharlack discloses a method of "determining and reporting the performance of VIS-IR spectrophotometers used to measure the concentration of hemoglobin components or fractions in blood samples." Col. 1, lines 51-54. Shaw, in contrast, discloses an "spectrophotometer apparatus which measures oxygen saturation of blood in vivo and which obviates the need for making [] reference measurements." Col. 1, lines 63-66. Scharlack discloses a method of calibrating a spectrophotometer used for *in vitro* measurements of blood samples. Shaw discloses

an apparatus which is used *in vivo* to measure blood parameters and avoids the need for additional reference measurements.

The Examiner suggested that the diodes of Shaw be employed in the apparatus of Scharlack. The Examiner does not, however, point to any disclosure or suggestion in the cited documents why one of skill in the art would look to the *in vivo* apparatus of Shaw to supply the radiation source for the *in vitro* apparatus of Scharlack. That, however, was the Examiner's burden. Having failed to provide the requisite evidence or reasoning to support the combination of the cited documents, the rejection failed to set forth a *prima facie* case for obviousness. Accordingly, the rejection should be withdrawn for this reason also.

Claim 42 was rejected under 35 USC § 103(a) as being unpatentable over Scharlack in view of Shaw and in view of Shepherd and further in view of Carim et al., U.S. Patent No. 5,553,615 ("Carim").. (Paper No. 10 at 7.)

For the reasons set forth below the rejection, respectfully is traversed.

Scharlack is summarized above.

Shaw is summarized above.

Shepherd is summarized above.

Carim discloses "a method and apparatus for the mechanically noninvasive, rapid, direct and accurate prediction of hematocrit using photoplethysmography." Col. 2, lines 31-33. Carim discloses that "incandescent light in the range of 300 nm to greater than 20,000 nm from [an incandescent lamp] is periodically interrupted by a 10 cm (4 inch) diameter disc rotating at high speed about 1 cm above the lamp that has pie-shaped open sectors for transmission of light.... "

Col. 14, lines 49-53. Carim further discloses the structure and operation of the disc as follows:

The disc is preferably made from a metal such as aluminum and preferably has two diametrically-opposed open pie sectors of about 66° opening each. Thus, the disc blocks light during about 228° of each revolution. It is within the scope of the invention to vary either the rotation speed or the amount of blockage, size, and number of the open sectors in order to adjust the amount and duration of light passing disc. It is also within the scope of the invention to use opto-electronic shutters such as those that vary the light transmitted through them between various levels depending on the applied electrical signal and at the rate of change of the applied signal.

The light from the lamp is "chopped" for several reasons. The "chopping" of the optical beam using open pie-shaped sectors on disc unexpectedly reduces excess heating of mammalian tissue that could alter the conditions affecting a noninvasive, transcutaneous prediction of hematocrit. Col. 14, line 53 - col. 15, line 4.

In making the rejection the Examiner asserted that "Scharlack in view of Shaw and Shepherd discloses everything as above (see claim 41)." (Paper No. 10 at 7.) The Examiner acknowledged however, that Scharlack, Shaw, ands Shepard "are silent concerning temperature activation." (Paper No. 10 at 7.)

To fill the acknowledged gap, the Examiner asserted that "Carim in an apparatus for prediction of hematocrit [discloses] temperature activation of a light source in order to prevent unnecessary heating of the sample being investigated (col. 14, lines 20-67; col. 15, lines 1-35)." (*Id.*) The Examiner then concluded that "it would be obvious to one skilled in the art at the time the invention was made to have the light source temperature activated in order to prevent unnecessary heating of the sample being investigated." (*Id.* at 8.)

Initially we note that our previous argument as to claim 41 applies with equal force to the rejection of claim 42. As previously noted, the rejection of claim 41 is deficient for numerous reasons. The rejection of claim 42 is, itself, deficient because it expressly relied on the rejection of claim 41 and provides nothing to remedy these deficiencies. For this reason alone the rejection is deficient and must be withdrawn.

As noted above, the claimed invention as a whole must be considered to make out a *prima facie* case for obviousness. The Examiner, however, has not considered claim 42 as a whole. Instead the Examiner merely referenced his earlier rejection of claim 41 and asserted that the limitations of claim 42 were found in Carim. Accordingly, claim 42 was considered only in parts and not as a whole. For this additional reason the rejection should be withdrawn.

Moreover, because the Examiner only considered claim 42 in parts, he failed to even assert that the claim as a whole was obvious. The Examiner concluded that "it would be obvious to one skilled in the art at the time the invention was made to have the light source temperature activated in order to prevent unnecessary heating of the sample being investigated." That is not what is claimed. What is claimed is a "quality control method" or a "spectrophotometer" with various recited characteristics.

As noted above, the Examiner is commanded to consider the claimed invention as a whole in making a rejection under 35 USC § 103. The Examiner, however, merely asserted that the alleged differences between the claimed invention and the cited document were obvious. Having failed to consider the claimed invention as a whole, the rejection failed to even assert that the claimed invention was obvious. For this additional reason the rejection is deficient and should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). Scharlack, Shaw, Shepard, and Carim, even if combined as suggested by the Examiner, do not disclose or suggest what is claimed in claim 42. Nowhere in any of the cited documents is there a disclosure or suggestion of "a neon lamp which is activated when the temperature of the spectrometer deviates more than a critical temperature difference." That, however, is what is claimed.

The Examiner asserted that "Carim in an apparatus for prediction of hematocrit [discloses] temperature activation of a light source in order to prevent unnecessary heating of the sample being investigated." The Examiner apparently misapprehended the disclosure of Carim.

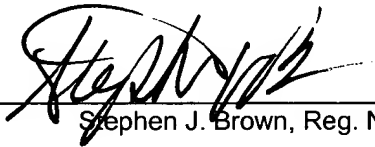
Carim does not disclose the activation of a lamp in response to a temperature differential. Carim discloses that an incandescent lamp "is periodically interrupted by a 10 cm (4 inch) diameter disc rotating at high speed about 1 cm above the lamp that has pie-shaped open sectors for transmission of light...." Col. 14, lines 49-53. Carim discloses that the disc "is preferably made from a metal such as aluminum and preferably has two diametrically-opposed open pie sectors of about 66° opening each. Thus, the disc blocks light during about 228° of each revolution. It is within the scope of the invention to vary either the rotation speed or the amount of blockage, size, and number of the open sectors in order to adjust the amount and duration of light passing disc." Col. 14, lines 50-61.

Accordingly, the lamp is always activated and the disc may be utilized to block the light produced by the lamp. That is not what is claimed. Nothing in Carim (or

the other cited documents) discloses or suggests the activation of a neon lamp when a critical temperature deviation is sensed. Accordingly, the cited documents fail to disclose or suggest each and every element of the claimed invention. For this reason too, the rejection is deficient and should be withdrawn.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections and objection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 16, 2004.



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